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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,439	09/10/2003	John J. Venit	18217-504-CON	7504
7590 03/25/2004				
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. One Financial Center Boston, MA 02111			EXAMINER REYES, HECTOR M	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

10/660,439

**Applicant(s)**

VENIT ET AL.

**Examiner**

Hector M Reyes

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**Restriction/Election Request**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, and 9-12, drawn to a series of compounds of formula I, and compositions comprising the same, ***wherein the variable Q is an optionally substituted aliphatic organic amine containing at least one nitrogen atom which, together with a proton, forms a quaternary ammonium cation QH<sup>+</sup>, classified in class 564, subclass 463+.***
- II. Claims 1, 5, 6, 9, 13 and 14 drawn to a series of compounds of formula I, and compositions comprising the same, ***wherein the variable Q is an amino acid containing at least two nitrogen atoms where one of the nitrogen atoms, together with a proton, forms a quaternary ammonium cation QH<sup>+</sup>, classified in class 562, subclass 553+.***
- III. Claims 1, 7-8 and 9, 14, 15 and 16 drawn to a series of compounds of formula I, and compositions comprising the same, ***wherein the variable Q is an amino acid containing one or more nitrogen atoms where one of the nitrogen atoms, together with a proton, forms a quaternary ammonium cation QH<sup>+</sup> and where, further, all carboxylic acid groups of the amino acid are in the form of esters, classified in class 560, subclass 155+.***
- IV. Claims 17-24, drawn to a method of modulating tumor growth or metastasis in an animal comprising administration of compound of formula I, ***wherein the variable Q is an optionally substituted aliphatic organic***

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***amine containing at least one nitrogen atom which, together with a proton, forms a quaternary ammonium cation  $QH^+$ , classified in class 514, subclass 014+.***

- V Claims 17 drawn to a method of modulating tumor growth or metastasis in an animal comprising administration of compound of formula I, ***wherein the variable Q is an amino acid containing at least two nitrogen atoms where one of the nitrogen atoms, together with a proton, forms a quaternary ammonium cation  $QH^+$ , classified in class 514, subclass 002+.***
- VI Claim 17, drawn to a method of modulating tumor growth or metastasis in an animal comprising administration of compound of formula I, ***wherein the variable Q is an amino acid containing one or more nitrogen atoms where one of the nitrogen atoms, together with a proton, forms a quaternary ammonium cation  $QH^+$  and where, further, all carboxylic acid groups of the amino acid are in the form of esters, classified in class 514, subclass 506+.***
- VII Claims 25-26, drawn to compositions as described in the said claims, classified in class 562, subclass 430+.
- VIII Claims 27-28 A method for preparing a compound of formula I, classified in class 562, subclass 430+.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I through III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions in groups I is different from inventions II and III because each invention drawn to compounds and its pharmaceutical compositions having a particular chemical structure.

Inventions in claims VI through VII are unrelated because each method of a method of modulating tumor growth or metastasis in an animal comprising administration of compounds with a particular chemical formula.

Inventions VII through VIII are different from each other because while invention VII is directed to a composition, the other group (VIII) is a different preparation of compounds. Each one of the above Inventions are different from each other because a given reference anticipating or suggesting one of the inventions under the meaning of 35 USC 102 or 35 USC 103, respectively, cannot be used to reject any of the other invention under 35 USC 102 or 35 USC 103.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any one of the above Groups is not required for anyone of the other Groups, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Groups I through VI are generic to a plurality of disclosed patentably distinct species comprising:

- In Group I and IV, different aliphatic amines
- In Groups II and VII, different amino acids
- In Groups III and VIII, different ester derivatives of amino acids.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (571) 272-0961. The examiner can normally be reached on M-F (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rita Desai can be reached on (571) 272-0684. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Hector M. Reyes PhD JD  
Reg. # 54,846  
AU 1625  
March 22, 2004

A handwritten signature in cursive script, appearing to read "RDesai", with a horizontal line underneath.

**RITA DESAI  
PRIMARY EXAMINER**